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Docket No. GJE-7452  
Serial No. 10/507,268Remarks

Claims 1-12 were previously pending in the subject application. By this Amendment, the applicants have amended claims 1 and 6 and have cancelled claims 10-12. Support for the amendments can be found throughout the subject specification and claims as originally filed. No new matter has been added by this Amendment. Accordingly, claims 1-9 are currently before the Examiner. Favorable consideration of the claims now presented is respectfully requested.

The applicants appreciate the Examiner's indication that the issues with regard to the sequences has been resolved and the objection withdrawn. The applicants also appreciate the Examiner's withdrawal of the previous rejection under 35 U.S.C. §112, first paragraph and his restatement/clarification of the issues in a new rejection under 35 U.S.C. §112, first paragraph.

The claim amendments set forth herein have been done in order to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendment and cancellation of the claims should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1-12 have been rejected under 35 U.S.C. §112, first paragraph. The applicants respectfully traverse this ground for rejection because the skilled artisan having the benefit of the applicants' disclosure would be able to readily make and use, without undue experimentation, the modified baculovirus as claimed.

Please note that claims 10-12 have been cancelled herein in order to expedite prosecution. Thus, the aspects of the rejection under 35 U.S.C. §112 that pertain to *in vivo* uses have been rendered moot. Accordingly, in this Response the applicants focus on the ability of the skilled artisan to make and use the claimed modified baculoviruses wherein modifications are made other than those that are specifically exemplified in the subject application.

The applicants respectfully submit that the techniques exemplified in the current application could be readily, and without undue experimentation, applied to other capsid proteins. Specifically, once the desirability of modifying the capsid is appreciated (as taught by the current applicant), the skilled person would have no difficulty in carrying out the invention. The cited prior art shows that

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the capsid can readily be sequenced; therefore, any desired modification can also be made. Once the modifications are made, it would be straightforward, utilizing the procedures set forth in the subject application to confirm that the desired modified baculovirus has been obtained.

It should be noted that the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . A considerable amount of experimentation is permissible, if it is merely routine . . ." (emphasis added). *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). In the current case, any experimentation needed to make other modifications would be routine given the guidance provided in the subject application.

The applicants respectfully submit that their own data, as well as the published scientific literature, provide a reasonable expectation that peptides other than the vp39 can be used. For example, as noted in the applicants' previous Response, Oker-Blom *et al.* ("Technique Reviews: Baculovirus display strategies: Emerging tools for eukaryotic libraries and gene delivery," *Briefing and Functional Genomics and Proteomics* 2(3):244-253, 2003) state:

Recently, a novel molecular biology tool was established by the development of baculovirus surface display, using different strategies for presentation of foreign peptides and proteins on the surface of budded virions. This eukaryotic display system enables presentation of large complex proteins on the surface of baculovirus particles and has thereby become a versatile system in molecular biology. Moreover, baculovirus capsid display has recently been developed; this holds promise for intracellular targeting of the viral capsid and subsequent cytosolic delivery of desired protein moieties. (Abstract)

At page 245, the Oker-Blom *et al.* go on to state:

Expression of proteins or peptides on the baculoviral surface, or more recently also on the viral capsid, without comprising replication in insect cells, has shown to be useful for important applications, both *in vivo* and *in vitro*. (citations omitted)

At pages 245-246 the authors further observe that:

Baculoviruses can accommodate large DNA insertions and grow to high titres, making them satisfactory for the generation of display libraries representing a variety of complex proteins, such as cell surface receptors, viral glycoproteins, ion channels or enzyme complexes, in a stable and functional form.

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In addition to these observations made by third parties, the inventors have data showing that p24 can also be used as a fusion partner in a baculovirus capsid display system.

The applicants acknowledge that it is conceivable that certain constructs may not result in the desired modified baculovirus. However, it is well established in the patent law that the mere possibility of an inoperable embodiment does not render a claim non-enabled. "It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). Furthermore, it is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. (BNA) 214, 218 (CCPA 1976). Thus, in the absence of any specific reason to doubt the ability of one skilled in the art to practice the subject invention, the applicants respectfully submit that the invention, as claimed, is fully enabled.

In summary, there is no reason to doubt that the applicants' teachings can be readily, and without undue experimentation, applied to produce modified baculoviruses will apply as currently claimed. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 1-7, 10 and 11 have been rejected under 35 U.S.C. §102(b) as being anticipated by *Liu et al.* (Acta Virolgia 44:157-161, 2000). The applicants specifically traverse this ground for rejection because *Liu et al.* do not disclose or suggest a baculovirus having a modified capsid that displays one or more heterologous peptides.

Please note that the claims have been amended herein to lend greater clarity to the claimed subject matter. Specifically, the applicants' claims require that the baculovirus capsid display one or more peptides that are heterologous to the baculovirus. Thus it is clear that these heterologous peptides are not present in (or the same as) the naturally occurring capsid. *Liu et al.* does not disclose any such modified baculovirus.

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It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Liu *et al.* do not disclose (or even suggest) the claimed modified baculovirus. Accordingly, because the cited reference does not disclose each and every element of the claimed invention, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Liu *et al.* reference.

Claims 10 and 12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Van Loo *et al.* (Journal of Virology 75(2):961-970, 2001). Please note that claims 10-12 have been cancelled herein thereby rendering moot this ground for rejection.

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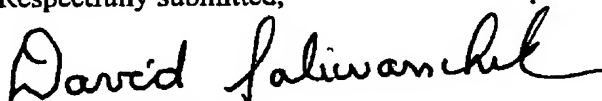
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In view of the foregoing remarks, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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